National Yogurt Association

November 6, 2006

Patricia N. Daniels
Director, Supplemental Food Programs Division
Food and Nutrition Service
United States Department of Agriculture
3101 Park Center Drive, Room 528
Alexandria, VA 22302

Re: Comments to the Proposed Rule on Revisions in the WIC Food Packages (Docket No. 0584-AD77, WIC Food Packages Rule)

Dear Ms. Daniels:

The National Yogurt Association ("NYA") is pleased to submit these comments to the United States Department of Agriculture's ("USDA" or "agency") Food and Nutrition Service ("FNS") in response to the proposed rule on the "Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Revisions in the WIC Food Packages" ("proposed rule") published in the *Federal Register* of August 7, 2006.[1]

NYA is the national nonprofit trade association representing producers of live and active culture ("LAC") yogurt products as well as suppliers to the yogurt industry. NYA's member companies are among the largest yogurt manufacturers in the United States. NYA sponsors scientific research regarding the health benefits associated with the consumption of yogurt with LAC and serves as an information resource for the American public about these attributes.

Live & Active Cultures

2000 CORPORATE RIDGE, SUITE 1000, McLEAN, VA 22102, USA TELEPHONE (703) 821-0770 FAX (703) 821-1350

[1] 71 Fed. Reg. 44784 (August 7, 2006).

Although NYA applauds USDA's efforts to modernize the WIC program and align WIC food packages with the 2005 Dietary Guidelines for Americans, NYA strongly objects to the agency's decision to exclude yogurt as a proposed partial alternative to fluid milk in WIC food packages. As discussed in greater detail below, the proposed rule and USDA's decision to exclude yogurt:

- Is inconsistent with the National Academies' Institute of Medicine's ("IOM") nutritionally-based and extensively researched recommendation that yogurt be included as a partial-substitute to fluid milk in WIC food packages;

- Does not comprehensively consider the unique nutritional and other benefits of yogurt to the WIC population;

- Is inconsistent with WIC's statutory requirement to focus the WIC program on supplemental foods that contain nutrients that address the nutritional risks of the WIC population;

- Is inconsistent with the purpose of authorized milk substitutes; and

- Does not include a statutorily required risk assessment by USDA's Office of Risk Assessment and Cost-Benefit Analysis ("ORACBA").

NYA respectfully requests that USDA include yogurt as an authorized alternative to fluid milk in WIC food packages. At the very least, USDA should: (1) conduct both a risk assessment and pilot test to assess the health effects and cost impact of including yogurt in the WIC food packages; and (2) consider alternatives such as the inclusion of yogurt only in Food Packages V-VII to facilitate the adoption of yogurt within the cost and nutrition parameters of the program.

I. Background on the WIC Program and Food Packages

The WIC program is one of the largest nutrient-focused and nutrition-based food assistance programs in the United States. Through the WIC program, the FNS provides Federal grants to States for supplemental foods, health care referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children who are found to be at *nutritional risk*.[2] Two types of nutrition risk are recognized for WIC

[2] 71 Fed. Reg. at 44785.

eligibility – medically based risks such as anemia or history of pregnancy complications, and dietary risks including inappropriate nutritional practices or the failure to meet dietary guidelines.[3]

Seven different WIC food packages provide supplemental foods designed to address the nutritional needs of WIC participants.[4] These supplemental foods currently include iron-fortified infant formula, iron-fortified cereals, fruit juice, vegetable juice, milk, cheese, eggs, peanut butter, dried beans, peas, carrots, tuna fish, and physician-prescribed formula/medical foods.[5] These foods are high in protein, calcium, iron, vitamin A, and/or vitamin C – nutrients that were identified in early legislation for the WIC program as being "of particular concern for WIC participants."[6] Most WIC participants access the food packages by redeeming vouchers or food-checks at participating retail outlets.

The USDA is now proposing to revise the WIC food packages to, among other things, "better reflect current nutrition science and dietary recommendations," support improved nutrient intakes, and provide increased variety and choice to WIC participants.[7] The proposed revisions are ostensibly based on the recommendations of the IOM, which was commissioned by the FNS to independently review the WIC packages and propose cost-neutral changes. However, the USDA does not fully incorporate the carefully reasoned and researched nutrition-based IOM recommendations into its proposed rule.

A. IOM's Recommended Changes to WIC Food Packages for Women

Following extensive research and analysis, the IOM identified certain "priority nutrients" that are lacking in the WIC population. Based on these priority nutrients, the IOM proposed a variety of

---

[3] USDA, "Nutrition Program Facts: The Special Supplemental Nutrition Program for Women, Infants, and Children," WIC Fact Sheet, (http://www.fns.usda.gov/wic/aboutwic/default.htm).

[4] 71 Fed. Reg. at 44787. There are currently seven different monthly packages - Food Package I is for infants 0-3 months, Food Package II is for infants 4-12 months, Food Package III is for children and women with special dietary needs, Food Package IV is for children 1-5 years of age, Food Package V is for pregnant and breastfeeding women, Food Package VI is for non-breastfeeding postpartum women, and Food Package VII is for breastfeeding women who elect not to receive infant formula through WIC for their infants.

[5] *Id.*

[6] *Id.*

[7] 71 Fed. Reg. at 44784.

cost-neutral changes to WIC food packages that are both culturally suitable and efficient for nationwide distribution and checkout.[8]

The IOM designated a nutrient as a priority nutrient if the prevalence of dietary inadequacy is non-trivial, the mean intake is below the Adequate Intake ("AI") values, or there is a recognized nutrition-related health priority.[9] For pregnant, lactating, and non-breastfeeding postpartum women, the IOM identified calcium, magnesium, vitamin E, potassium, and fiber as "priority nutrients."[10] Nutrients with moderate, but still high, levels of inadequacy for this group were determined to be vitamins A, C, and B6, and folate.[11] Nutrients with lower levels of inadequacy were iron, zinc, thiamin, niacin, and protein.[12]

In light of these priority nutrients, the IOM recommended a variety of changes to the three food packages intended for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women without special dietary needs. Compared with current food packages, the IOM recommended that all three revised food packages for women provide smaller amounts of eggs and juice; add a requirement that cereals be whole grain; and add fruits and vegetables via a $10 fruit and vegetable voucher. Whole grain bread or other whole grains would be added to two of the three packages. Canned light tuna would continue to be allowed in one of the food packages, but canned salmon and sardines would be authorized as substitutes for light tuna.[13]

---

[8] As noted in the preamble to the proposed rule, the IOM used "current scientific information to assess the nutrient adequacy of the diets of WIC participants; assess the supplemental nutrition needs of the population served by WIC; look at the nutrient contributions of the current packages; propose priority nutrients and general nutritional recommendations; and make recommendations for specific changes to the WIC food packages." The IOM used various data sources and examined nutrition-related health risks to identify nutrients and food groups to try to increase or decrease in the food packages with the goal of improving the nutrition of WIC participants. The review of the WIC food packages was further informed by extensive comments made in response to an Advanced Notice of Proposed Rulemaking ("ANPR") on revisions to the WIC food packages, and by comments received by the IOM in public forums during its review. *Id.*

[9] 71 Fed. Reg. at 44787.

[10] 71 Fed. Reg. at 44788.

[11] *Id.*

[12] *Id.*

[13] 71 Fed. Reg. at 44796.

In addition, all three food packages for women would provide smaller amounts of milk products, no longer authorize whole milk, and would allow several alternatives to milk in order to accommodate cultural preferences and to help ensure adequate calcium intake by those who cannot consume milk due to lactose intolerance.[14] Notably, the IOM recommended that: (1) reduced-fat yogurt be permitted as a partial substitute for fluid milk for children and women; (2) cheese continue to be permitted as a partial substitute for fluid milk for children and women; (3) calcium-set tofu be permitted as a partial substitute for fluid milk for women; and (4) soy beverage be permitted as an alternative for all or part of the fluid milk for women.[15] To maintain the nutritional content and cost neutrality of the food packages, the IOM recommended that some substitutions for milk (*i.e.*, yogurt, calcium-set tofu, cheese) be allowed only in limited amounts.[16] The IOM permitted these limitations to be waived in cases of lactose intolerance or other medical conditions.

The IOM conducted a cost-analysis as part of its review and believed that its recommendations to revise the WIC food packages were relatively cost-neutral. The IOM also acknowledged that although the proposed changes are expected to have beneficial effects, some of them could cause unintended and undesirable consequences. Accordingly, the IOM urged the USDA to conduct pilot testing and randomized, controlled trials of the changes before they are implemented nationwide.[17]

B. Overview of the Proposed Rule

The USDA did not adopt all of the IOM's carefully reasoned nutrition-based recommendations because the agency claims that implementing them in full would cost $1.3 billion above the cost-neutral level over five years. To achieve cost-neutrality, the agency proposed two key modifications: (1) a cash-value fruit and vegetable voucher $2 less per month than that recommended by the IOM; and (2) the removal of yogurt as a proposed alternative to milk.[18]

---

[14] *Id.*

[15] IOM, "WIC Food Packages: Time for a Change," at 119 (http://www.fns.usda.gov/oane/MENU/Published/WIC/WIC.htm). Tofu and soy beverages are not allowed as substitutions for milk in the children's package except when prescribed in writing by a recognized medical authority.

[16] *Id.* at 119-200.

[17] *Id.* at 4.

[18] 71 Fed. Reg. at 44786.

The agency argued that the price of yogurt as compared to the price of milk would considerably increase the monthly cost of the food packages for children and women.[19] USDA does not, however, thoroughly articulate the basis for the cost estimates of including yogurt, or otherwise demonstrate that the estimates are based upon expected program participant purchases of the type of yogurt in the same quart sizes recommended by IOM. Although soy beverages and tofu also have higher per unit costs than milk, the agency believes that "the estimated amount of these products that would be purchased by WIC participants is substantially lower than that of yogurt."[20]

USDA also deviated from the IOM recommendations with respect to the standards for defining allowable soy-based beverages. The IOM recommended allowing as milk alternatives only soy-based beverages that are fortified to contain nutrients in amounts similar to cow's milk. The IOM also recommended minimum levels per cup of 300 mg of calcium and 120 International Units ("IU") of vitamin D.[21] USDA, however, proposed lower levels of minimum nutrients for authorized soy beverages. For example, the USDA proposed 276 mg of calcium per cup and 100 IU of vitamin D per cup – both of which are lower than the IOM standard.[22]

In addition to these substantive deviations from the IOM nutrient recommendations, the proposed rule does *not* incorporate the IOM's strong recommendation that the USDA conduct pilot testing or other trials of the changes before they are implemented nationwide.

As discussed in greater detail below, USDA's proposed rule and decision to exclude yogurt: (1) does not comprehensively consider the unique nutritional benefits of yogurt to the WIC population; (2) is inconsistent with WIC's statutory purpose and the purpose of authorized milk substitutes; and (3) does not include a statutorily required risk assessment by ORACBA. The USDA should consider alternatives that include yogurt in the food packages, and conduct pilot tests to assess the health effects and cost impact of including yogurt in the WIC food packages.

II. Pregnant and Breastfeeding Women Have a Critical Need for Increased Calcium and the Other Nutrients That Yogurt Provides

---

[19] 71 Fed. Reg. at 44847. USDA priced yogurt at $2.62 per quart, as compared to $.68 per quart for milk.

[20] 71 Fed. Reg. at 44786.

[21] 71 Fed. Reg. at 44801.

[22] *Id.*

The USDA should adopt the IOM's recommendation that yogurt be authorized as a proposed alternative to fluid milk. Yogurt is a nutritious food that is widely available throughout the country and in urban and rural areas alike. It is unclear, and USDA has not addressed, whether fortified soy is or would be similarly available to program participants. In addition, yogurt is a good alternative for those who are lactose intolerant, or who avoid milk for cultural or other reasons. Moreover, yogurt provides significant amounts of potassium and calcium - two of the priority nutrients identified by the IOM for pregnant and breastfeeding women.

A. Nutritional Benefits of Yogurt

Yogurt is a nutrient dense food that contains many essential minerals and vitamins, including riboflavin (Vitamin B2), Vitamin B12, phosphorous and potassium. In addition, yogurt is a good source of protein and calcium. A single serving of yogurt provides between 5 - 10 grams of protein, or 10 to 20% of the Daily Recommended Value ("DRV").

Yogurt is also commonly known as an excellent source of calcium, which is important in developing and maintaining strong, healthy bones and helps to regulate blood pressure in women during pregnancy.[23] In fact, the IOM determined that insufficient calcium intake for pregnant and breastfeeding women may be associated with potential lead toxicity for the fetus and infant.[24]

The 2005 Dietary Guidelines for Americans notes that studies specifically on milk and other milk products, such as yogurt and cheese, showed a positive relationship between the intake of milk and milk products and bone mineral content or bone mineral density in one or more skeletal sites.[25] Recent studies also suggest that increasing calcium may reduce the risk of colon cancer.[26] Some yogurts contain up to 35% of the Recommended Daily Intake ("RDI") for calcium.

B. Additional Benefits Associated With Live and Active Cultures

---

[23] Shield, Jodie, "The Importance of Dietary Calcium," (http://www.aboutyogurt.com/expertsCorner/shieldCalcium.asp).

[24] IOM, "WIC Food Packages: Time for a Change," at 62.

[25] Department of Health and Human Services, and USDA, "Dietary Guidelines for Americans," chapter 5, page 26 (2005).

[26] Shield, Jodie, "The Importance of Dietary Calcium," (http://www.aboutyogurt.com/expertsCorner/shieldCalcium.asp).

In addition to the high nutritional value offered by yogurt, research indicates that the LACs in yogurt may offer additional health benefits. As required under the current yogurt standard of identity, yogurt must be cultured with *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, although yogurt products may and often do contain other LACs in addition to the standard cultures required by the standard of identity.[27]

Research suggests that certain specific strains of LACs may, depending on the strain, play an active role in preventing gastrointestinal infections,[28] fighting certain types of cancer,[29] boosting the body's immune system,[30] and reducing nasal allergies.[31] The medical community also recognizes the health benefits of consuming yogurt. A magazine conducted a survey and polled 565 physicians across the country to assess whether they believed there were health benefits associated with the regular consumption of active cultures.[32] The survey found that two out of three doctors who counsel their patients on nutritional issues recommend live and active cultured yogurt for: (1) its overall nutritional health benefits; (2) finding it helpful in maintaining a healthy intestinal system; and (3) as a tolerable source of dairy calcium for those who are lactose intolerant.[33]

C. Yogurt is a Good Alternative for Those Who Are Lactose Intolerant

Research also has confirmed that during the fermentation process required under the standard of identity, LACs play an active role in breaking down lactose in milk, thus allowing those who are

---

[27] 21 C.F.R §§ 131.200, 131.203, and 131.206.

[28] "Getting to Know Yogurt," *Food Management*, July 1, 2004 at 65.

[29] RK Peters et. al, "Diet and Colon Cancer in Los Angeles County," *Cancer Causes Control*, 3(5): 457-473 (Sept. 3, 1992) (Results from a study of over 1,400 subjects with colon cancer that sought to determine which foods were associated with a reduced risk of colon cancer indicated that yogurt intake is associated with a significantly decreased risk of colon cancer); Oskar Adolfsson et. al, "Yogurt and Gut Function," *American Journal of Clinical Nutrition*, 80(2): 245-56 (Aug. 2004).

[30] Martine Piaia et. al, "Assessment of the Benefits of Live Yogurt: Methods and Markers for in vivo Studies of the Physiological Effects of Yogurt Cultures," *Microbial Ecology in Health and Disease*, 15: 79-87, 82 (Nov. 2003).

[31] *Id.*

[32] "Nutrition: Doctors Who Discuss Nutrition With Their Patients Often Recommend Yogurt," *Obesity, Fitness & Wellness Week via NewsRx.com and NewsRx.net* (December 29, 2001 – January 5, 2002).

[33] *Id.*

lactose intolerant to eat yogurt without certain side effects such as bloating and diarrhea.[34] The IOM similarly recognized that individuals with lactose maldigestion were able to tolerate yogurt better than milk, and that "a high prevalence of lactose maldigestion and low cultural acceptability have been widely cited as reasons for the low consumption of dairy products among people of color."[35] In fact, the IOM noted that Asians and African Americans are especially at risk for low intakes of dietary calcium, and that milk and cheese are not a part of the traditional food patterns of many cultural groups.[36] The IOM highlighted the fact that in public comments, yogurt, soy milk, and tofu were *frequently requested* as calcium-rich options.

The IOM's findings are particularly important since a significant number of women and children enrolled in the WIC program are represented by racial and ethic minorities. In fact, USDA noted in the preamble to the proposed rule that "marked demographic changes have occurred, with both a dramatic increase in the number of persons served by WIC and a substantial shift in the ethnic composition of the WIC population."[37] The IOM's recommendation to revise the WIC food packages to include reduced-fat yogurt as an alternative to milk would provide an acceptable source of calcium for those WIC participants with lactose maldigestion, and for those who avoid milk for cultural, religious, or other reasons.

III. USDA's Decision to Exclude Yogurt Is Inconsistent with WIC's Statutory Purpose

Not only is yogurt a widely available food that provides priority nutrients to the WIC population, but USDA's decision to exclude yogurt as a proposed alternative to milk is inconsistent with WIC's statutory purpose. The WIC program was developed to provide supplemental foods and nutrition education to its participants and to *"improve the health status of these persons."*[38] Supplemental foods are defined to include "those foods containing *nutrients* determined by *nutritional research to be lacking* in the diets of pregnant, breastfeeding, and postpartum women, infants, and children . . ."[39] The legislative history of the WIC program is similarly replete with

---

[34] *Id.* at 80; Oskar Adolfsson et. al, "Yogurt and Gut Function" at 245-56.

[35] IOM, "WIC Food Packages: Time for a Change," at 119.

[36] *Id.*

[37] 71 Fed. Reg. at 44787.

[38] 42 USC § 1786(a) (emphasis added).

[39] 42 USC § 1786(b)(14) (emphasis added). The IOM also recognized that the goal of the WIC program "is to improve birth outcomes, support the growth and development of infants and children, and promote long-term health in all WIC participants." IOM, "WIC Food Packages: Time for a Change," at 1.

references to WIC's focus on providing supplemental nutrients that are found to be lacking in the WIC population.[40]

It is important to note that the focus of the WIC program is on supplemental foods that provide *nutrients* that are found lacking in the diets of participants - not on the *foods* that are found lacking. In fact, the 1994 amendments changed the name of the WIC program from the "Special Supplemental *Food* Program for Women Infants and Children" to the "Special Supplemental *Nutrition* Program for Women, Infants, and Children," further emphasizing the program's focus on improving nutrition for certain at-risk populations.[41] From this perspective, it is difficult to discern the rationale for permitting participants to buy a product that contains very little to no

---

[40] For example, the Congressional findings of the Child Nutrition Act note that substantial numbers of the WIC eligible population are "at special risk with respect to the physical and mental health by reason of inadequate nutrition, health care, or both." 42 USC § 1786(a). The purpose of the program is to provide program participants with supplemental foods, which are "those foods containing nutrients determined by nutritional research to be lacking in the diets" of program participants. *Id.* at 1786(b)(14). The House of Representatives Committee Report on proposed amendments to child nutrition laws noted that WIC "is a nutrition supplementation program that makes funds available . . . for the purpose of providing supplemental foods to low-income women, infants and children as an adjunct to good health care." H.R. Rep. No. 95-1153, pt. 1, at 2-3 (1978). The 1994 Senate Committee Report on amendments to the Child Nutrition Act of 1966 highlighted the WIC program's positive impact on health in the target populations, explaining that:

> WIC provides nutritious food, nutrition education and health care referrals to low-income women and their children up to age five. WIC has been shown to reduce infant mortality and the incidence of low-birthweight among newborns. In addition, every dollar spent on the prenatal component of WIC saves up to $4 in Medicaid costs for medical problems arising within 60 days after birth. S. Rep. No. 103-300, at 2 (1994).

Championing the importance of pre-natal and child nutrition programs like WIC, the Senate report asserted that "[p]roper nutrition not only improves health, it also saves money." *Id.* at 4. The report's section-by-section analysis of proposed legislation amending child nutrition legislation underscored the WIC program's success in improving health for target populations, declaring that "WIC helps prevent low birthweight, reduces anemia and increases childhood immunizations." *Id.* at 36.

The Senate Committee Report on the bill that became the Child Nutrition and WIC Reauthorization Act of 2004 explained that WIC "provides nutrition services and tailored food packages" to certain populations "who are judged to be at nutritional risk." S. Rep. No. 108-279, at 2 (2004). The Child Nutrition and WIC Reauthorization Act of 2004's amendments to the WIC provision accentuate the program's goal of improving health through better nutrition. The Act amended the definition of "supplemental foods" to include those foods "containing nutrients determined by nutritional research to be lacking in the diets of pregnant, breastfeeding, and postpartum women, infants, and children and foods that promote the health of the population served by the program . . . ." P. L. 108-265, section 203(a)(2) (2004).

[41] P.L. 103-448, § 204(w)(1)(B) (1994) (emphasis added).

high priority nutrients, such as iceberg lettuce, while precluding them from buying a product like yogurt, which is specifically recommended as an alternate product for a high priority nutrient found lacking in program participants.

Although NYA is sympathetic to the programmatic concerns related to placing limits on the types of fruits and vegetables permitted in WIC food packages, and is also supportive of increasing fruit and vegetable consumption, NYA believes that USDA is statutorily required to focus the WIC program on those supplemental foods that contain nutrients that address the nutritional risks of the WIC program population. A general goal of increasing consumption of fruits and vegetables in the WIC population, however worthy of public support, is not the same as targeting resources to address areas of nutritional risk, which is FNS' mandate under the Child Nutrition Act.

The USDA itself has recognized that "inadequate *nutrition* was the prime motivating factor behind enactment of the WIC program,"[42] and that "foods have always been selected for WIC food packages based on their *nutrient density*, modest cost, wide availability, and broad acceptability by the WIC-eligible population."[43] However, despite the fact that the IOM identified calcium as a "priority nutrient" for the WIC population and recommended yogurt as a good source of such calcium, the USDA failed to authorize yogurt as a proposed alternative to milk.

Without data explicitly showing the level at which WIC program participants would purchase the size and type of yogurt recommended by IOM, USDA claimed that it was necessary to exclude yogurt in order to maintain cost neutrality. USDA, however, includes soy and tofu as proposed alternatives to fluid milk specifically because fewer program participants will select them as alternatives. For USDA to disregard one calcium replacement, namely yogurt, a widely recognized source of calcium for the US population, because allegedly too many participants would select it, and to include another, namely soy-based products which need to be fortified with calcium, specifically because they will be less popular among participants, is fundamentally inconsistent with WIC's statutory goal to target nutrient risks in program participants and improve their health status.

IV. USDA's Decision to Exclude Yogurt is Inconsistent With the Purpose of Authorized Milk Substitutes

---

[42] 71 Fed. Reg. at 44824.

[43] *Id.* (emphasis added).

USDA's decision to exclude yogurt is also inconsistent with the purpose of authorized milk substitutes. The IOM proposed partial and full alternatives to fluid milk in order to provide WIC participants who have milk allergies or lactose maldigestion (or for those who avoid milk for cultural, religious, or other reasons) with more acceptable sources of calcium.[44] To maintain cost neutrality, some of the authorized substitutes are only allowed in limited amounts. If the purpose of the milk substitutes is to provide greater variety and choice to WIC participants, it is counterintuitive to provide substitutes that are less widely available, and that would (according to the agency) be used less than yogurt.

Moreover, the USDA proposes nutritional standards for soy milk that the agency acknowledges are "*currently not met by many products on the market.*"[45] As a result, WIC participants are not being provided any real meaningful choice and the agency is not doing enough to encourage sufficient consumption of calcium rich foods. For all practical purposes, the proposed USDA WIC packages will not result in a greater diversity of dairy foods selected by WIC participants as suggested by the IOM report. This is particularly significant in light of: (1) the IOM's finding that calcium is a priority nutrient for which program participants are critically deficient; and (2) the fact that USDA's proposed fortification level of calcium in soy milk (276 mg of calcium per cup) is lower than that recommended by the IOM (300 mg of calcium per cup).[46]

USDA explained its deviation from the IOM's nutrition-based recommendation for soy fortification by claiming that the proposed nutritional standards for soy milk in WIC packages should be consistent with the nutritional standards for soy milk in the National School Lunch Program and the School Breakfast Program.[47] However, there is no statutory mandate that requires USDA to disregard the IOM recommendations. In fact, USDA failed to recognize that WIC program participants and school nutrition program participants have different nutritional needs, and the authorizing statutes of the two programs do not require identical soy standards. In order to ensure that WIC program participants receive the levels of priority nutrients they need, USDA should simply follow the fortification levels recommended by IOM.

---

[44] 71 Fed. Reg. at 44799.

[45] 71 Fed. Reg. at 44835 (emphasis added).

[46] The IOM recommended minimum levels per cup of 300 mg of calcium and 120 IU of vitamin D. The USDA, however, proposed 276 mg of calcium per cup and 100 IU of vitamin D per cup – both of which are lower than the IOM standard.

[47] 71 Fed. Reg. at 44801.

Not only is USDA's decision to exclude yogurt inconsistent with WIC's statutory purpose and the purpose of authorized milk substitutes, but the agency completely failed to conduct a required risk assessment that could have uncovered nutritional risks and explored alternatives to provide the largest amount of priority nutrients to the WIC population at a cost-neutral level.

V. USDA Failed To Conduct a Risk Assessment As Required by Law

USDA agencies are required to conduct a risk assessment of, among other things, any "proposed major regulation the primary purpose of which is to regulate issues of human health . . ."[48] This includes "an analysis with as much specificity as practicable" of:

- the risk to human health addressed by the regulation;
- the costs of the regulation;
- a comparison of the risk to other similar risks; and
- the benefits of the regulation.[49]

USDA failed to conduct a risk assessment of the WIC proposed rule, which is a "major regulation" that has a primary purpose of regulating issues of human health. The proposed rule is accompanied only by a regulatory impact analysis ("RIA") that does not contain the required risk assessment.

Given USDA's role in developing the recommendations for the revised food packages, it would be appropriate for the agency to solicit views on the best way to contain costs and address the nutritional risks of program participants.

A. The Proposed Rule is a Major Rule Requiring a Risk Assessment

USDA agencies are required to conduct a risk assessment under 7 USC § 2204e(b)(1) of any proposed major regulation. A "major" rule is one that "the Secretary . . . estimates is likely to have an annual impact on the economy . . . of $100,000,000 in 1994 dollars."[50] The proposed WIC rule is plainly "major," with costs well over $100 million per year in 1994 dollars. In fact, the RIA discusses the major cost drivers of the proposed rule, many of which individually exceed

---

[48] 7 USC § 2204e(b)(1).

[49] 7 USC § 2204e(b)(1)(A)-(D).

[50] 7 USC § 2204e(c).

the $100 million threshold. For example, the reduction in formula in Food Package I is estimated to save $367 million, the reduction of milk in Food Package IV is estimated to save $956 million, the addition of fruits and vegetables is estimated to cost $1.372 billion, and whole grains are estimated to cost $639 million.[51] All told, the Federal food costs for WIC for fiscal year 2005 were $3.6 billion.

B. The Primary Purpose of the Proposed Rule is to Regulate Issues of Human Health

Not only is the WIC proposed rule a "major" regulation, but the rule's preamble and WIC's statutory authority reveal that the primary purpose of the proposed rule is to regulate issues of human health - in particular the health of WIC program participants.

For example, the proposed rule notes that the IOM "examined *nutrition-related health risks* to identify nutrients and food groups to try to increase or decrease in the food packages with the goal of improving the nutrition of WIC participants."[52] The proposed rule also notes that "WIC is a unique nutrition assistance program in that it also serves as an adjunct to good health care during critical times of growth and development *to prevent the occurrence of health problems* and to *improve the health status* of Program participants."[53]

In discussing whether to exempt small entities from the requirements of the proposed rule, the rule states that:

> Exempting small entities from providing the specific foods intended to address the nutritional needs of participants or altering the requirements for small entities would *undermine the purpose of the WIC Program and endanger the health status of participants.*[54]

While NYA is not taking a position on the exemption of small entities, the agency's language demonstrates that the WIC rule is squarely focused on regulating human health. Indeed, the entire point of the rulemaking is to improve the nutrient intake of WIC program participants by

---

[51] 71 Fed. Reg. at 44839.

[52] 71 Fed. Reg. at 44784 (emphasis added).

[53] 71 Fed. Reg. at 44785 (emphasis added).

[54] 71 Fed. Reg. at 44810 (emphasis added).

revising the food packages. The fact the proposed rule is focused on regulating human health is also consistent with the underlying statutory authorities for the WIC program, which (as discussed in Section III) are replete with references to WIC's focus on providing supplemental nutrients that are lacking in program participants.

Indeed, with its special focus on providing a targeted set of nutrients to address special risks to a specific population, the WIC proposed rule falls squarely within the types of rules that Congress believed should be subject to the risk assessment requirements. In the House of Representatives' Committee Report on what was then called the "Office of Environmental Risk," which became ORACBA in the enacted law, Congress noted that only regulations "specifically designed to mitigate particular . . . risks" were covered by the risk assessment requirement.[55] Unlike the food stamp program, WIC is clearly directed at addressing a particular set of risks – the nutritional risks of the WIC population.

Even USDA officials have acknowledged the need for a risk assessment. In presentations to the IOM, USDA officials from ORACBA indicated that the proposed food package revisions need to have a risk assessment completed as part of the rulemaking process.[56] ORACBA's own statement to the IOM outlined two different potential ways to measure nutritional deficiency, each of which would have resulted in different food packages.[57]

Congress enacted ORACBA in order to ensure that USDA agencies conducted risk assessments to improve the quality and effectiveness of USDA regulations. The WIC food packages have not been revised for decades, and the choices and challenges facing FNS are immense, as it seeks to improve the delivery of nutrients to the WIC population through a revised WIC food package, but without adequate funds to provide the full array of foods containing the recommended priority nutrients.

This rulemaking is precisely the type that Congress intended to be subject to a risk assessment, which would undoubtedly assist the agency in making more science-based and transparent decisions about how best to allocate limited funding and improve the delivery of key nutrients to program participants.

---

[55] H.R. Rep. No. 103-714, pt. 1, at 35 (1994).

[56] James D. Schaub, February 26, 2004 USDA/ORACBA Presentation, "Regulatory Risk Assessment: Special Supplemental Nutrition Program for Women, Infants and Children Food Packages," (http://www.iom.edu/CMS/3788/18047/18314/18317/19297.aspx).

[57] *Id.*

C. A Risk Assessment Would Help Ensure That the WIC Program Provides the Most Nutritional Bang for the Buck

Given the need for cost containment, a risk assessment that analyzes various options for allocating the limited amount of funding to program participants would provide invaluable guidance in ensuring that the program provides the most nutritional bang for the buck. It is possible, for example, that a different formulation of packages that include yogurt and only certain nutrient rich types of fruits and vegetables could mitigate nutrition risks better than the proposed packages.

Moreover, USDA made no effort to analyze the risk impact of its decision to allow soy and tofu as milk alternatives, despite IOM's recommendation to include soy, tofu, and yogurt. It is by no means clear that program participants for whom calcium is a critical deficiency will select soy or tofu at the same rate that they would select yogurt. The lack of a nutritional risk assessment is doubly problematic because USDA failed to require that soy beverages be fortified to the levels required by IOM.

The failure to include yogurt in the proposed food packages appears to be solely driven by the need to contain costs. As noted in the RIA, however, other options could have been pursued in order to control costs. The absence of a risk assessment analyzing the impact of various food packages and cost containment scenarios on program participants suggests that FNS had a set of preferred outcomes for the revised food packages - outcomes that were not necessarily based on providing "priority nutrients" to program participants, but on promoting a certain set of food products at the expense of others.

This is unfortunate for both taxpayers and participants. WIC is a very important public health program that will spend tens of billions of taxpayer dollars over the coming years. USDA should ensure that it is spending that money in a way that best addresses the nutritional risks of program participants, and the best way to do that is to conduct a risk assessment examining the impact of various options. Policy makers will still have room to make policy judgments, but those judgments can be informed by, and analyzed in, the context of a complete and transparent assessment of various risks and outcomes.

Given USDA's role in developing the recommendations for the revised food packages, it would be appropriate for the agency to solicit views on the best way to contain costs and address the nutritional risks of program participants.

VI. USDA Should Conduct Pilot Tests to Assess the Health Effects and Cost Impact of Including Yogurt in the WIC Food Packages

In addition to conducting a risk assessment, USDA should conduct pilot tests to assess the health effects and cost impact of including yogurt in the WIC food packages. USDA should not arbitrarily restrict access to an IOM recommended calcium substitute without evidence showing that it would in fact have a significant impact on cost. Despite IOM's recommendations to include yogurt in the food packages and to conduct pilot tests of the revised food packages, USDA excludes yogurt and refuses to conduct pilot tests, claiming that it lacks authority to conduct such pilot studies. USDA, however, proposes to utilize a staggered implementation plan for certain provisions, which will effectively operate as a pilot program since it will allow USDA to gauge the impact and cost of the new provisions before they are implemented nationally.

Specifically, the RIA notes that:

> Key provisions of the rule intended to promote breastfeeding will be implemented initially in no more than 32 local test sites in up to eight states. *Those provisions will not be implemented nationwide until FNS has evaluated their effectiveness at the test sites.*[58]

Why should FNS utilize what is effectively a pilot program approach for the breastfeeding provisions, but refuse to do so for any other provisions of the proposed rule? This disparate treatment is without justification, particularly in light of the IOM recommendations for pilot programs.

Moreover, the IOM identifies calcium as a priority nutrient for women in the WIC program, and recommended yogurt, cheese, tofu, and fortified soy as alternative means for women to get the amount of calcium they need. USDA has no baseline data regarding the extent to which program participants would select yogurt. From the RIA, it is unclear if the assumptions about the extent of yogurt consumption by program participants are based on consumer purchases of quarts of yogurt or individual size yogurts. This is significant because consumer data clearly shows that consumers purchase quart size yogurt at much lower levels than individual size yogurt.[59]

---

[58] 71 Fed. Reg. at 44845 (emphasis added).

[59] For one NYA member company, for example, the dollar sales of single serving yogurt (less than 16 ounces) over the past year were $1,679,013,000. Meanwhile, the dollar sales of quart sized yogurt over this period were $296,997,200.

In addition, it is possible that a much smaller percentage of WIC participants will select tofu or soy beverages as an alternative to fluid milk, and there is no guarantee that available soy beverage will be sufficiently fortified to qualify under the WIC program.

Although NYA understands that there are cost challenges to making revisions to the WIC food packages, there must be better ways to ensure that FNS is providing the best nutrition in the most cost effective manner possible than to simply exclude yogurt altogether. USDA should implement pilot programs or a staggered implementation approach that would allow FNS to analyze the actual extent to which participants would select cheese, soy beverage, tofu, or yogurt instead of milk. USDA could then use data from these pilots or other implementation approaches to make appropriate revisions to the food packages. In other words, a pilot-based or staggered approach would give USDA data to help shape the final packages in a way that best meets participant needs with the limited program funding available. If USDA needs statutory authority to conduct such an approach, NYA believes that USDA could readily obtain such authority from Congress.

VII. USDA Should Pursue Alternatives That Include Yogurt In the Food Packages

The test programs discussed above would give USDA actual cost data on which to base revisions to the food packages, and would allow USDA to have a more solid sense of the cost impacts of including yogurt. This would be the most preferred approach, coupled with the risk assessment discussed above.

In general, however, there are other options that USDA could consider that would allow the inclusion of yogurt in the food packages. For example, since the IOM identified calcium as a priority nutrient for women, USDA could limit yogurt to the food packages intended for women (Food Packages V-VII) instead of Food Packages IV-VII. This could provide some cost savings.

Similarly, limiting or reducing foods that no longer provide higher priority nutrients in WIC food packages could provide cost savings that could be allocated to yogurt. As previously noted, while NYA is both supportive of increasing fruit and vegetable consumption and is sympathetic to the programmatic challenges related to focusing for inclusion in WIC food packages those fruits and vegetables that provide higher priority nutrients, NYA believes that USDA is statutorily required to focus the WIC program on those supplemental foods that contain nutrients that address the nutritional risks of the WIC program population.

VIII. Conclusion

NYA respectfully requests that USDA include yogurt as an authorized alternative to fluid milk in WIC food packages. Yogurt provides significant amounts of potassium and calcium - two of the priority nutrients identified by the IOM for pregnant and breastfeeding women. In addition, yogurt is a good dairy option for those who are lactose intolerant, or who avoid milk for cultural or other reasons. At the very least, USDA should: (1) conduct a risk assessment and pilot test (or staggered implementation approach) to assess the health effects and cost impact of including yogurt in the WIC food packages; (2) consider alternatives such as the inclusion of yogurt only in Food Packages V-VII to facilitate the adoption of yogurt within the cost and nutrition parameters of the program; and (3) explore other options such as limiting or reducing foods that no longer provide priority nutrients to fund and incorporate yogurt in WIC food packages.

Respectfully submitted,

Leslie G. Sarasin

Leslie G. Sarasin
President
National Yogurt Association

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

CLINICAL REPORT

Lactose Intolerance in Infants, Children, and Adolescents

Guidance for the Clinician in Rendering Pediatric Care

Melvin B. Heyman, MD, MPH, for the Committee on Nutrition

ABSTRACT

The American Academy of Pediatrics Committee on Nutrition presents an updated review of lactose intolerance in infants, children, and adolescents. Differences between primary, secondary, congenital, and developmental lactase deficiency that may result in lactose intolerance are discussed. Children with suspected lactose intolerance can be assessed clinically by dietary lactose elimination or by tests including noninvasive hydrogen breath testing or invasive intestinal biopsy determination of lactase (and other disaccharidase) concentrations. Treatment consists of use of lactase-treated dairy products or oral lactase supplementation, limitation of lactose-containing foods, or dairy elimination. The American Academy of Pediatrics supports use of dairy foods as an important source of calcium for bone mineral health and of other nutrients that facilitate growth in children and adolescents. If dairy products are eliminated, other dietary sources of calcium or calcium supplements need to be provided.

INTRODUCTION

SIGNIFICANT CHANGES IN our knowledge and approach toward lactose intolerance have occurred over the past quarter century, since the first statement on lactose intolerance was published by the American Academy of Pediatrics Committee on Nutrition.[1] Lactose ingestion in certain susceptible individuals can cause abdominal symptoms that are variable and can be treated with dietary restriction or enzyme replacement, depending on the amount of lactose consumed and the degree of lactase deficiency. Pediatricians and other pediatric care providers should maintain awareness of the benefits and controversies related to the consumption of dietary milk products and milk-based infant formula. The lactose content of milk often influences, correctly or not, the ultimate decision about the use or continuation of milk in the diet. Milk and dairy-product avoidance has a negative effect on calcium and vitamin D intake in infants, children, and adolescents. Other nutrients such as protein make dairy products an important source of nutrition for growing children. This revised statement will update the initial statement of 1978 while incorporating changes from the 1990 supplement[2] and current state-of-the-art relating to lactose intolerance. Recommendations regarding dietary calcium have been updated recently.[3]

Lactose, a disaccharide that comprises the monosaccharides glucose and galactose, is the primary carbohydrate found exclusively in mammalian milk. Absorption of lactose requires lactase activity in the small intestinal brush border to split the bond linking the 2 monosaccharides. A β-galactosidase termed "lactase-phlorizin hydrolase" (lactase) accounts for most of the lactase activity in the intestinal

www.pediatrics.org/cgi/doi/10.1542/peds.2006-1721

doi:10.1542/peds.2006-1721

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Key Words

abdominal pain, breath tests, calcium, dietary, dairy products, diarrhea, flatulence, lactase, malabsorption, pediatric

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

mucosa.[4] Lactase is found in the small intestine and localized to the tips of the villi, a factor of clinical importance when considering the effect of diarrheal illness on the ability to tolerate milk.

Milk intolerance may be attributed to either the lactose or the protein content. Lactose intolerance can occur among infants and young children with acute diarrheal disease, although the clinical significance of this is limited except in more severely affected children. Symptoms of lactose intolerance are relatively common among older children and adolescents; however, associated intestinal injury is infrequently seen. Lactose intolerance is a distinct entity from cow milk–protein sensitivity, which involves the immune system and causes varying degrees of injury to the intestinal mucosal surface. Cow milk–protein intolerance is reported in 2% to 5% of infants within the first 1 to 3 months of life, typically resolves by 1 year of age, and is not the subject of this statement.[5,6]

DEFINITIONS

Following are definitions of terms used in the remainder of this statement:

- Lactose intolerance is a clinical syndrome of 1 or more of the following: abdominal pain, diarrhea, nausea, flatulence, and/or bloating after the ingestion of lactose or lactose-containing food substances. The amount of lactose that will cause symptoms varies from individual to individual, depending on the amount of lactose consumed, the degree of lactase deficiency, and the form of food substance in which the lactose is ingested.
- Lactose malabsorption is the physiologic problem that manifests as lactose intolerance and is attributable to an imbalance between the amount of ingested lactose and the capacity for lactase to hydrolyze the disaccharide.
- Primary lactase deficiency is attributable to relative or absolute absence of lactase that develops in childhood at various ages in different racial groups and is the most common cause of lactose malabsorption and lactose intolerance. Primary lactase deficiency is also referred to as adult-type hypolactasia, lactase nonpersistence, or hereditary lactase deficiency.
- Secondary lactase deficiency is lactase deficiency that results from small bowel injury, such as acute gastroenteritis, persistent diarrhea, small bowel overgrowth, cancer chemotherapy, or other causes of injury to the small intestinal mucosa, and can present at any age but is more common in infancy.
- Congenital lactase deficiency is extremely rare; teleologically, infants with congenital lactase deficiency would not be expected to survive before the 20th century, when no readily accessible and nutritionally adequate lactose-free human milk substitute was available.
- Developmental lactase deficiency is now defined as the relative lactase deficiency observed among preterm infants of less than 34 weeks' gestation.

Primary Lactase Deficiency

Approximately 70% of the world's population has primary lactase deficiency.[7,8] The percentage varies according to ethnicity and is related to the use of dairy products in the diet, resulting in genetic selection of individuals with the ability to digest lactose (Table 1). In populations with a predominance of dairy foods in the diet, particularly northern European people, as few as 2% of the population has primary lactase deficiency. In contrast, the prevalence of primary lactase deficiency is 50% to 80% in Hispanic people, 60% to 80% in black and Ashkenazi Jewish people, and almost 100% in Asian and American Indian people.[9–11] The age of onset and its prevalence differ among various populations. Approximately 20% of Hispanic, Asian, and black children younger than 5 years of age have evidence of lactase deficiency and lactose malabsorption,[12] whereas white children typically do not develop symptoms of lactose intolerance until after 4 or 5 years of age. Recent molecular studies of lactase-phlorizin hydrolase (lactase) have correlated the genetic polymorphism of messenger RNA expression with persistence of lactase activity, demonstrating early loss (at 1–2 years of age) of messenger RNA expression and enzyme activity in Thai children and late (10–20 years of age) loss of activity in Finnish children.[11,13] The clinical relevance of these observations is that children with clinical signs of lactose intolerance at an earlier age than is typical for a specific ethnic group may warrant an evaluation for an underlying cause, because primary lactase deficiency would otherwise be unusual at such a young age. Although primary lactase deficiency may present with a relatively acute onset of milk intolerance, its onset typically is subtle and progressive over many years. Most lactase-

TABLE 1 Prevalence of Acquired Primary Lactase Deficiency[69]

Examples of groups among whom lactase deficiency predominates (60%–100% lactase deficient)
Near East and Mediterranean: Arabs, Ashkenazi Jews, Greek Cypriots, Southern Italians
Asia: Thais, Indonesians, Chinese, Koreans
Africa: South Nigerians, Hausa, Bantu
North and South America: black Americans, Latinas, Eskimos, Canadian and American Indians, Chami Indians
Examples of groups among whom lactase persistence predominates (2%–30% lactase deficient)
Northern Europeans
Africa: Hima, Tussi, Nomadic Fulani
India: individuals from Punjab and New Delhi

deficient individuals experience onset of symptoms in late adolescence and adulthood.

Reports that focus on clinical symptoms of lactase deficiency are prone to subjectivity, confounding clinical diagnosis. For instance, when lactase-deficient adults were given 2 glasses of milk or 2 glasses of lactose-hydrolyzed milk per day in a double-blind, crossover study, no statistical differences in symptoms of lactose intolerance were found regardless of whether the individual described himself or herself as lactose intolerant.[14] Even lactose-intolerant adults may find that 1 glass of milk or a scoop of ice cream is tolerated, whereas an additional glass of milk or other milk product may produce symptoms. Because of the variation of dairy intake in each individual's diet and in the amount of lactose contained in different products, symptoms may vary and be modified by diet and by milk-containing foods (see "Management"). For these reasons, dietary history is an unreliable means to confirm or exclude the diagnosis of lactose intolerance.

Secondary Lactase Deficiency

Secondary lactase deficiency implies that an underlying pathophysiologic condition is responsible for the lactase deficiency and subsequent lactose malabsorption. Etiologies include acute infection (eg, rotavirus) causing small intestinal injury with loss of the lactase-containing epithelial cells from the tips of the villi. The immature epithelial cells that replace these are often lactase deficient, leading to secondary lactose deficiency and lactose malabsorption, although several reports indicate that lactose malabsorption in most children with acute gastroenteritis is not clinically important.[15] Several recent studies and a meta-analysis found that children with rotaviral (and other infectious) diarrheal illnesses who have no or only mild dehydration can safely continue human milk or standard (lactose-containing) formula without any significant effect on outcome, including hydration status, nutritional status, duration of illness, or success of therapy.[16–18] However, in the at-risk infant (eg, younger than 3 months or malnourished) who develops infectious diarrhea, lactose intolerance may be a significant factor that will influence the evolution of the illness. Giardiasis, cryptosporidiosis, and other parasites that infect the proximal small intestine often lead to lactose malabsorption from direct injury to the epithelial cells by the parasite. Secondary lactase deficiency with clinical signs of lactose intolerance can be seen in celiac disease, Crohn disease, and immune-related and other enteropathies and should be considered in these children. Diagnostic evaluation should be directed toward these entities when secondary lactase deficiency is suspected and an infectious etiology is not found.

Young infants with severe malnutrition develop small intestinal atrophy that also leads to secondary lactase deficiency.[19] Although uncommon in the United States, malnutrition is associated with lactose malabsorption and carbohydrate intolerance in developing countries.[20] Lactose malabsorption has also been associated with poor growth in these countries.[21] Most infants and children with malabsorption attributable to malnutrition are able to continue to tolerate dietary carbohydrates, including lactose.[22] However, the World Health Organization recommends avoidance of lactose-containing milks in children with persistent postinfectious diarrhea (diarrhea lasting more than 14 days) when they fail a dietary trial of milk or yogurt.[23]

Treatment of secondary lactase deficiency and lactose malabsorption attributable to an underlying condition generally does not require elimination of lactose from the diet but, rather, treatment of the underlying condition. Once the primary problem is resolved, lactose-containing products can often be consumed normally, and these excellent sources of calcium and other nutrients need not be unnecessarily excluded from the diet.

Developmental (Neonatal) Lactase Deficiency

In the immature gastrointestinal tract, lactase and other disaccharidases are deficient until at least 34 weeks' gestation.[24] One study in preterm infants reported benefit from use of lactase-supplemented feedings or lactose-reduced formulas,[25] and the use of lactose-containing formulas and human milk does not seem to have any short- or long-term deleterious effects in preterm infants.[26] Up to 20% of the dietary lactose may reach the colon in neonates and young infants. Bacterial metabolism of colonic lactose lowers the fecal pH (5.0–5.5 is normal), which has a beneficial effect, favoring certain organisms (eg, *Bifidobacterium* and *Lactobacillus* species) in lieu of potential pathogens (*Proteus* species, *Escherichia coli*, and *Klebsiella* species) in young infants. Antimicrobial agents may also affect this colonization.

Congenital Lactase Deficiency

Congenital lactase deficiency is a rare disorder that has been reported in only a few infants.[27,28] Affected newborn infants present with intractable diarrhea as soon as human milk or lactose-containing formula is introduced. Small intestinal biopsies reveal normal histologic characteristics but low or completely absent lactase concentrations.[29,30] Unless this is recognized and treated quickly, the condition is life-threatening because of dehydration and electrolyte losses. Treatment is simply removal and substitution of lactose from the diet with a commercial lactose-free formula.

DIAGNOSIS

Symptoms of lactose intolerance, including abdominal distention, flatulence, abdominal cramping, and (ultimately) diarrhea, are independent of the cause of lactose malabsorption and are directly related to the quantity of ingested lactose. These symptoms are not necessarily

correlated with the degree of intestinal lactase deficiency. Malabsorbed lactose generates an osmotic load that draws fluid and electrolytes into the intestinal lumen, leading to loose stool. The onset of diarrhea and other symptoms is related to the amount of lactose that is not absorbed. As little as 12 g of lactose (the amount of lactose in an 8-oz glass of milk) may be sufficient to cause symptoms in children with chronic abdominal pain.[31] In addition, unabsorbed lactose is a substrate for intestinal bacteria, especially in the colon. Bacteria metabolize lactose, producing volatile fatty acids and gases (methane, carbon dioxide, and hydrogen), leading to flatulence. The fatty acids lower the fecal pH, making the fecal pH test a nonspecific but sometimes helpful marker for lactose (or other carbohydrate) malabsorption. When sufficient intestinal gas is produced by the bacterial metabolic processes to cause stimulation of the intestinal nervous system by intestinal distention, visceral (abdominal) cramping results.

Initial studies using lactose hydrogen breath tests documented lactose malabsorption in up to 40% of children and adolescents presenting with abdominal pain.[32] However, recent studies suggest that the prevalence of abdominal symptoms related to lactose intolerance documented by hydrogen breath tests is variable and ranges from 2% in Finnish children to 24% in southern US children.[33,34]

A good clinical history often reveals a relationship between lactose ingestion and symptoms. When lactose intolerance is suspected, a lactose-free diet can be tried (Tables 2 and 3).[35] During a diagnostic lactose-free diet, it is important that all sources of lactose be eliminated, requiring the reading of food labels to identify "hidden" sources of lactose. Generally, a 2-week trial of a strict lactose-free diet with resolution of symptoms and subsequent reintroduction of dairy foods with recurrence of symptoms can be diagnostic. In more-subtle cases, the hydrogen breath test is the least invasive and most helpful test to diagnose lactose malabsorption. The test has been shown to be more reliable than history, because some patients think they are lactose intolerant when they prove not to be, and others prove to be lactose intolerant (lactose malabsorbers) when they think they are not.[36,37] The test is performed by administration of a standardized amount of lactose (2 g/kg, up to a maximum of 25 g, equivalent to the amount of lactose in 2 8-oz glasses of milk) after fasting overnight and then measuring the amount of hydrogen in expired air over a 2- to 3-hour period. An increase (>20 ppm) in the hydrogen expired after approximately 60 minutes is consistent with lactose malabsorption. Factors that may produce false-negative or false-positive results include conditions affecting the intestinal flora (eg, recent use of antimicrobial agents), lack of hydrogen-producing bacteria (10%–15% of the population), ingestion of high-fiber diets before the test, small intestinal bacterial overgrowth, or intestinal motility disorders. A pediatric gastroenterologist should be consulted to interpret the results of this test.

TABLE 2 Lactose and Calcium Content of Common Foods[70,71]

Dairy Products	Calcium Content, mg	Lactose Content, g
Yogurt, plain, low fat, 1 cup	448	8.4
Milk, whole (3.25% fat), 1 cup	276	12.8
Milk, reduced fat, 1 cup	285	12.2
Ice cream, vanilla, 1/2 cup	92	4.9
Cheddar cheese, 1 oz	204	0.07
Swiss cheese, 1 oz	224	0.02
Cottage cheese, creamed (small curd), 1 cup	135	1.4

TABLE 3 Hidden Sources of Lactose[72]

Bread and other baked goods
Processed breakfast cereals
Mixes for pancakes, biscuits, and cookies
Instant potatoes, soups, and breakfast drinks
Margarine
Nonkosher lunchmeats
Salad dressings
Candies and other snacks

The older lactose-tolerance test was previously relied on as the primary test of lactose malabsorption before the breath hydrogen test became available. Lactose intolerance was diagnosed by onset of symptoms and/or positive test results after ingestion of a standard lactose dose (2 g/kg of body weight or 50 g/m^2 of body surface area; maximum 50 g in a 20% water solution). If the maximum increase in blood glucose concentration was less than 26 mg/dL after a lactose-tolerance test dose, lactose malabsorption was diagnosed. The lactose-tolerance test is not sensitive enough to determine if a subject is malabsorbing some lactose. It is also often falsely positive because of lack of an increase of blood glucose concentration attributable to normal insulin response to the carbohydrate load. Given the high rate of false-negative and false-positive results, this test should not be used and has been replaced by the hydrogen breath test.

Other tests are available in consultation with a pediatric gastroenterologist to diagnose lactose intolerance. If an underlying cause for secondary lactose intolerance is suspected, testing for intestinal etiologies includes stool examination, particularly for parasites affecting the upper gastrointestinal tract such as *Giardia lamblia* and *Cryptosporidia* species, and blood tests for celiac disease (ie, total immunoglobulin A concentration and antitissue transglutaminase antibody[38,39]) or immunodeficiency (quantitative immunoglobulins). Intestinal biopsy may be needed to uncover an underlying gastrointestinal mucosal problem that is causing the lactose malabsorption. Biopsies can yield direct measurement of disaccharidase concentrations to document lactase deficiency directly and assess the status of the other

brush-border disaccharidases (sucrase, maltase, isomaltase), which may also be deficient under various circumstances. However, intestinal lactase concentrations do not seem to correlate well with symptoms of lactose intolerance.[40]

Newer tests may eventually yield additional detailed information pertaining to the prevalence and significance of lactose intolerance.[41] For example, the [^{13}C]lactose breath test is being considered as a test to augment the accuracy of the breath hydrogen test but is still primarily an investigational tool.[42,43]

In infants with diarrhea in whom lactose (or other carbohydrate) intolerance is suspected, stool can be screened for malabsorbed carbohydrate by testing fecal pH, which decreases with carbohydrate malabsorption as a result of the formation of volatile fatty acids. It should be remembered that fecal pH will normally be lower (5.0–5.5) in infants compared with older children and adolescents because of the physiologic overload of lactose in their diets, which in turn helps to favor growth of *Lactobacillus* species in the colon. Fecal reducing substances can also be measured and become positive by excretion of a reducing sugar in the stools. Reducing sugars include lactose, glucose, fructose, and galactose but not sucrose. Because some patients may only malabsorb enough carbohydrates, such as lactose, to lower the fecal pH but not increase excretion of carbohydrate in the stool, the pH test is a more sensitive test for carbohydrate malabsorption.

MANAGEMENT

When children are diagnosed with lactose intolerance, avoidance of milk and other dairy products will relieve symptoms. However, those with primary lactose intolerance have varying degrees of lactase deficiency and, correspondingly, often tolerate varying amounts of dietary lactose. Lactose-intolerant children (and their parents) should realize that ingestion of dairy products resulting in symptoms generally leads to transient symptoms without causing harm to the gastrointestinal tract (as compared with celiac disease or allergic reactions, including milk-protein intolerance, that can lead to ongoing inflammation and mucosal damage). Although lactose malabsorption does not predispose to calcium malabsorption,[44] avoidance of milk products to control symptoms may be problematic for optimal bone mineralization. Children who avoid milk have been documented to ingest less-than-recommended amounts of calcium needed for normal bone calcium accretion and bone mineralization.[45,46]

Lactose-free and lactose-reduced milks (and lactose-free whole milk for children younger than 2 years) are widely available in supermarkets and can be obtained with WIC (Special Supplemental Nutrition Program for Women, Infants, and Children) vouchers. Although lactose-free milk is more expensive than regular milk, some major chain stores sell less-expensive lactose-free milk under their own brand names.

Beyond infancy, substitutes for cow milk based on rice, soy, or other proteins are readily available and are generally free of lactose, although the nutrient content of most of these milks is not equivalent to cow milk. Other mammalian milks, including goat milk, are not free of lactose. Tolerance to milk products may be partial, so that dietary maneuvers alone may help avoid symptoms in some individuals. Small amounts of lactose in portions of 4 to 8 oz spaced throughout the day and consumed with other foods may be tolerated with no symptoms.[47–51] Some children are able to drink 1 to 2 glasses of milk each day without difficulty but cannot tolerate more without developing symptoms.[14] Many lactose-intolerant individuals who are intolerant of milk can tolerate milk chocolate[52] and/or yogurt (plain better than flavored), because the bacteria in the yogurt partially digest the lactose into glucose and galactose before consumption.[53,54] In addition, yogurt's semisolid state slows gastric emptying and gastrointestinal transit, resulting in fewer symptoms of lactose intolerance.[55] Furthermore, ingestion of other solid foods delays gastric emptying, providing additional time for endogenous lactase to digest dietary lactose. Aged cheeses tend to have lower lactose content than other cheeses and, thus, may also be better tolerated. Finally, oral lactase-replacement capsules or predigested milk or dairy products with lactase are readily available and will often permit a lactose-intolerant individual to be able to take some or all milk products freely.[56] Because the vitamin D content in milk-substitute products varies, labels must be checked to verify the vitamin D content of individual brands.

Even among population groups with significant lactose intolerance, the importance of dietary dairy products has been stressed. For example, the National Medical Association recently recommended that black people consume 3 to 4 servings per day of low-fat milk, cheese, and/or yogurt and that lactose-free milk be used as an alternative for those who are intolerant of these other products to help reduce the risk of nutrient-related chronic diseases such as hypertension and diabetes.[57]

Milk and dairy products are often well tolerated by many children with underlying inflammatory conditions of the intestines, including Crohn disease and ulcerative colitis, in whom the prevalence of lactose intolerance does not seem to be any greater than in the general population.[58–61]

Lactose-Free Formulas

In developed countries, even in the case of acute gastroenteritis, enough lactose digestion and absorption are preserved so that low-lactose and lactose-free formulas have no clinical advantages compared with standard lactose-containing formulas except in severely undernourished children, in whom lactose-containing formu-

las may worsen the diarrhea and lactose-free formulas may be advantageous.[62] Breastfed infants should be continued on human milk in all cases.[57] This has also been reviewed recently in the American Academy of Pediatrics' practice guideline for acute gastroenteritis.[63] The use of lactase in formulas for preterm infants has been noted above. Although lactose-free cow milk–protein-based formulas are readily available and popular, no studies have documented that these formulas have any clinical impact on infant outcome measures including colic, growth, or development.[64]

Lactose, Calcium Absorption, and Bone Mineral Content

Recent evidence indicates that dietary lactose enhances calcium absorption and, conversely, that lactose-free diets result in lower calcium absorption.[65] Thus, lactose intolerance (and lactose-free diets) theoretically may predispose to inadequate bone mineralization, a problem now recognized in many other disorders affecting pediatric patients.[45,46] The effects of lactose-free diets in childhood on long-term bone mineral content and risk of fractures and osteoporosis with aging remains to be clarified. Calcium homeostasis is also affected by protein intake, vitamin D status, salt intake, and genetic and other factors, making long-term studies essential to determine the risks of each or all of these to bone health. Recent studies suggest that in the future, genetic testing may be useful for identifying individuals at increased risk of lactase deficiency and consequent diminished bone mineral density,[66] potentially allowing early intervention with dietary manipulation or nutrient supplementation. Recent research has even suggested that gene-replacement therapies might someday be available for susceptible individuals.[67]

SUMMARY

Lactose intolerance has been recognized for many years as a common problem in many children and most adults throughout the world. Although rarely life-threatening, the symptoms of lactose intolerance can lead to significant discomfort, disrupted quality of life, and loss of school attendance, leisure and sports activities, and work time, all at a cost to individuals, families, and society. Treatment is relatively simple and aimed at reducing or eliminating the inciting substance, lactose, by eliminating it from the diet or by "predigesting" it with supplemental lactase-enzyme replacement. Calcium must be provided by alternate nondairy dietary sources or as a dietary supplement to individuals who avoid milk intake.

CONCLUSIONS

1. Lactose intolerance is a common cause of abdominal pain in older children and teenagers.
2. Lactose intolerance attributable to primary lactase deficiency is uncommon before 2 to 3 years of age in all populations; when lactose malabsorption becomes apparent before 2 to 3 years of age, other etiologies must be sought.
3. Evaluation for lactose intolerance can be achieved relatively easily by dietary elimination and challenge. More-formal testing is usually noninvasive, typically with fecal pH in the presence of watery diarrhea and hydrogen breath testing.
4. If lactose-free diets are used for treatment of lactose intolerance, the diets should include a good source of calcium and/or calcium supplementation to meet daily recommended intake levels.
5. Treatment of lactose intolerance by elimination of milk and other dairy products is not usually necessary given newer approaches to lactose intolerance, including the use of partially digested products (such as yogurts, cheeses, products containing *Lactobacillus acidophilus*, and pretreated milks[56,68]). Evidence that avoidance of dairy products may lead to inadequate calcium intake and consequent suboptimal bone mineralization makes these important as alternatives to milk. Dairy products remain principle sources of protein and other nutrients that are essential for growth in children.

REFERENCES

1. American Academy of Pediatrics, Committee on Nutrition. The practical significance of lactose intolerance in children. *Pediatrics*. 1978;62:240–245

2. American Academy of Pediatrics, Committee on Nutrition. Practical significance of lactose intolerance in children: supplement. *Pediatrics.* 1990;86:643–644
3. American Academy of Pediatrics, Committee on Nutrition. Optimizing bone health and calcium intake of infants, children, and adolescents. *Pediatrics.* 2006;117:578–585
4. Semenza G. Anchoring and biosynthesis of stalked brush border membrane proteins: glycosidases and peptidases of enterocytes and renal tubuli. *Annu Rev Cell Biol.* 1986;2:255–313
5. American Academy of Pediatrics, Committee on Nutrition. Hypoallergenic infant formulas. *Pediatrics.* 2000;106:346–349
6. Host A, Jacobsen HP, Halken S, Holmenlund D. The natural history of cow's milk protein allergy/intolerance. *Eur J Clin Nutr.* 1995;49(suppl 1):S13–S18
7. Kretchmer N. Lactose and lactase: a historical perspective. *Gastroenterology.* 1971;61:805–813
8. Kretchmer N. On the homology between human development and pediatrics. *Pediatr Res.* 1968;2:283–286
9. Paige DM, Bayless TM, Mellitis ED, Davis L. Lactose malabsorption in preschool black children. *Am J Clin Nutr.* 1977;30: 1018–1022
10. Lloyd ML, Olsen WA. Disaccharide malabsorption. In: Haubrich WS, Schaffner F, Berk JE, eds. *Bockus Gastroenterology.* 5th ed. Philadelphia, PA: Saunders; 1995:1087–1100
11. Sahi T. Genetics and epidemiology of adult-type hypolactasia. *Scand J Gastroenterol Suppl.* 1994;202:7–20
12. Woteki CE, Weser E, Young EA. Lactose malabsorption in Mexican-American children. *Am J Clin Nutr.* 1976;29:19–24
13. Wang Y, Harvey CB, Hollox EJ, et al. The genetically programmed down-regulation of lactase in children. *Gastroenterology.* 1998;114:1230–1236
14. Suarez FL, Savaiano D, Arbisi P, Levitt MD. Tolerance to the daily ingestion of two cups of milk by individuals claiming lactose intolerance. *Am J Clin Nutr.* 1997;65:1502–1506
15. Sandhu BK, Isolauri E, Walker-Smith JA, et al. A multicentre study on behalf of the European Society of Paediatric Gastroenterology and Nutrition Working Group on Acute Diarrhoea. Early feeding in childhood gastroenteritis. *J Pediatr Gastroenterol Nutr.* 1997;24:522–527
16. Bhatnagar S, Bhan MK, Singh KD, Saxena SK, Shariff M. Efficacy of milk-based diets in persistent diarrhea: a randomized, controlled trial. *Pediatrics.* 1996;98:1122–1126
17. Sperotto G, Barison EM, Baldacci ER, Okay Y. Use of undiluted whole cow's milk is effective for the routine treatment of children with acute diarrhea and severe dehydration. *Arq Gastroenterol.* 1998;35:132–137
18. Brown KH, Peerson JM, Fontaine O. Use of nonhuman milks in the dietary management of young children with acute diarrhea: a meta-analysis of clinical trials. *Pediatrics.* 1994;93: 17–27
19. Nichols BL, Dudley MA, Nichols VN, et al. Effects of malnutrition on expression and activity of lactase in children. *Gastroenterology.* 1997;112:742–751
20. Northrop-Clewes CA, Lunn PG, Downes RM. Lactose maldigestion in breast-feeding Gambian infants. *J Pediatr Gastroenterol Nutr.* 1997;24:257–263
21. Wharton B, Howells G, Phillips I. Diarrhoea in kwashiorkor. *Br Med J.* 1968;4:608–611
22. Habte D, Hyvarinen A, Sterky G. Carbohydrate malabsorption in kwashiorkor. *Ethiop Med J.* 1973;11:33–40
23. World Health Organization, International Working Group on Persistent Diarrhoea. Evaluation of an algorithm for the treatment of persistent diarrhoea: a multicenter study. *Bull World Health Organ.* 1996;74:479–489
24. Antonowicz I, Lebenthal E. Developmental patterns of small intestinal enterokinase and disaccharidase activities in the human fetus. *Gastroenterology.* 1977;72:1299–1303
25. Erasmus HD, Ludwig-Auser HM, Paterson PG, Sun D, Sankaran K. Enhanced weight gain in preterm infants receiving lactase-treated feeds: a randomized, double-blind, controlled trial. *J Pediatr.* 2002;141:532–537
26. Shulman RJ, Feste A, Ou C. Absorption of lactose, glucose polymers, or combination in premature infants. *J Pediatr.* 1995; 127:626–631
27. Lifshitz F. Congenital lactase deficiency. *J Pediatr.* 1966;69: 229–237
28. Savilahti E, Launiala K, Kuitunen P. Congenital lactase deficiency: a clinical study on 16 patients. *Arch Dis Child.* 1983; 58:246–252
29. Asp NG, Dahlqvist A, Kuitunen P, Launiala K, Visakorpi JK. Complete deficiency of brush-border lactase in congenital lactose malabsorption. *Lancet.* 1973;2(7824):329–330
30. Freiburghaus AU, Schmitz J, Schindler M, et al. Protein patterns of brush border fragments in congenital lactose malabsorption and in specific hypolactasia of the adult. *N Engl J Med.* 1976;294:1030–1032
31. Gremse DA, Greer AS, Vacik J, DiPalma JA. Abdominal pain associated with lactose ingestion in children with lactose intolerance. *Clin Pediatr (Phila).* 2003;42:341–345
32. Barr RG, Levine MD, Watkins JB. Recurrent abdominal pain of childhood due to lactose intolerance. *N Engl J Med.* 1979;300: 1449–1452
33. Kokkonen J, Haapalahti M, Tikkanen S, Karttunen R, Savilahti E. Gastrointestinal complaints and diagnosis in children: a population-based study. *Acta Paediatr.* 2004;93:880–886
34. Webster RB, DiPalma JA, Gremse DA. Irritable bowel syndrome and lactose maldigestion in recurrent abdominal pain in childhood. *South Med J.* 1999;92:778–781
35. Drugs.com. Lactose free diet. Available at: www.drugs.com/CG/LACTOSE_FREE_DIET.html. Accessed August 18, 2005
36. Di Palma JA, Narvaez RM. Prediction of lactose malabsorption in referral patients. *Dig Dis Sci.* 1988;33:303–307
37. Suarez FL, Savaiano DA, Levitt MD. A comparison of symptoms after the consumption of milk or lactose-hydrolyzed milk by people with self-reported severe lactose intolerance. *N Engl J Med.* 1995;333:1–4
38. Hill ID, Dirks MH, Liptak GS, et al. Guideline for the diagnosis and treatment of celiac disease in children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *J Pediatr Gastroenterol Nutr.* 2005;40: 1–19
39. National Institutes of Health. NIH consensus development conference on celiac disease. Available at: http://consensus.nih.gov/2004/2004CeliacDisease118html.htm. Accessed August 18, 2005
40. Gupta SK, Chong SK, Fitzgerald JF. Disaccharidase activities in children: normal values and comparison based on symptoms and histologic changes. *J Pediatr Gastroenterol Nutr.* 1999;28: 246–251
41. Vonk RJ, Lin Y, Koetse HA, et al. Lactose (mal)digestion evaluated by the 13C-lactose digestion test. *Eur J Clin Invest.* 2000; 30:140–146
42. Hiele M, Ghoos Y, Rutgeerts P, Vantrappen G, Carchon H, Eggermont E. $13CO_2$ breath test using naturally 13C-enriched lactose for detection of lactase deficiency in patients with gastrointestinal symptoms. *J Lab Clin Med.* 1988;112:193–200
43. Koetse HA, Stellaard F, Bijleveld CM, et al. Non-invasive detection of low-intestinal lactase activity in children by use of a combined $13CO_2/H_2$ breath test. *Scand J Gastroenterol.* 1999;34: 35–40
44. Tremaine WJ, Newcomer AD, Riggs BL, McGill DB. Calcium absorption from milk in lactase-deficient and lactase-sufficient adults. *Dig Dis Sci.* 1986;31:376–378
45. Stallings VA, Oddleifson NW, Negrini BY, Zemel BS, Wellens R.

Bone mineral content and dietary calcium intake in children prescribed a low-lactose diet. *J Pediatr Gastroenterol Nutr.* 1994; 18:440–445
46. Di Stefano M, Veneto G, Malservisi S, et al. Lactose malabsorption and intolerance and peak bone mass. *Gastroenterology.* 2002;122:1793–1799
47. McBean LD, Miller GD. Allaying fears and fallacies about lactose intolerance. *J Am Diet Assoc.* 1998;98:671–676
48. Johnson AO, Semenya JG, Buchowski MS, Enwonwu CO, Scrimshaw NS. Adaptation of lactose maldigesters to continued milk intake. *Am J Clin Nutr.* 1993;58:879–881
49. Hertzler SR, Savaiano DA. Colonic adaptation to the daily lactose feeding in lactose maldigesters reduces lactose intolerance. *Am J Clin Nutr.* 1996;64:232–236
50. Pribila BA, Hertzler SR, Martin BR, Weaver CM, Savaiano DA. Improved lactose digestion and intolerance among African-American adolescent girls fed a dairy-rich diet. *J Am Diet Assoc.* 2000;100:524–528
51. Hertzler SR, Huynh BC, Savaiano DA. How much lactose is low lactose? *J Am Diet Assoc.* 1996;96:243–246
52. Jarvinen RM, Loukaskorpi M, Uusitupa MI. Tolerance of symptomatic lactose malabsorbers to lactose in milk chocolate. *Eur J Clin Nutr.* 2003;57:701–705
53. Kolars JC, Levitt MD, Aouji M, Savaiano DA. Yogurt: an autodigesting source of lactose. *N Engl J Med.* 1984;310:1–3
54. Boudraa G, Benbouabdellah M, Hachelaf W, Boisset M, Desjeux JF, Touhami M. Effect of feeding yogurt versus milk in children with acute diarrhea and carbohydrate malabsorption. *J Pediatr Gastroenterol Nutr.* 2001;33:307–313
55. Labayen I, Forga L, Gonzalez A, Lenoir-Wijnkoop I, Nutr R, Martinez JA. Relationship between lactose digestion, gastrointestinal transit time and symptoms in lactose malabsorbers after dairy consumption. *Aliment Pharmacol Ther.* 2001;15: 543–549
56. Medow MS, Thek KD, Newman LJ, Berezin S, Glassman MS, Schwarz SM. Beta-galactosidase tablets in the treatment of lactose intolerance in pediatrics. *Am J Dis Child.* 1990;144: 1261–1264
57. Wooten WJ, Price W. The role of dairy and dairy nutrients in the diet of African Americans. *J Natl Med Assoc.* 2004;96(12 suppl):5S–31S
58. Pfefferkorn MD, Fitzgerald JF, Croffie JM, Gupta SK, Corkins MR, Molleston JP. Lactase deficiency: not more common in pediatric patients with inflammatory bowel disease than in patients with chronic abdominal pain. *J Pediatr Gastroenterol Nutr.* 2002;35:339–343
59. Kirschner BS, DeFavaro MV, Jensen W. Lactose malabsorption in children and adolescents with inflammatory bowel disease. *Gastroenterology.* 1981;81:829–832
60. Mishkin S. Dairy sensitivity, lactose malabsorption, and elimination diets in inflammatory bowel disease. *Am J Clin Nutr.* 1997;65:564–567
61. Bernstein CN, Ament M, Artinian L, Ridgeway J, Shanahan F. Milk tolerance in adults with ulcerative colitis. *Am J Gastroenterol.* 1994;89:872–877
62. Kukuruzovic RH, Brewster DR. Milk formulas in acute gastroenteritis and malnutrition: a randomized trial. *J Paediatr Child Health.* 2002;38:571–577
63. American Academy of Pediatrics, Provisional Committee on Quality Improvement, Subcommittee on Acute Gastroenteritis. Practice parameter: the management of acute gastroenteritis in young children. *Pediatrics.* 1996;97:424–435
64. Heubi J, Karasov R, Reisinger K, et al. Randomized multicenter trial documenting the efficacy and safety of a lactose-free and a lactose-containing formula for term infants. *J Am Diet Assoc.* 2000;100:212–217
65. Abrams SA, Griffin IJ, Davila PM. Calcium and zinc absorption from lactose-containing and lactose-free infant formulas. *Am J Clin Nutr.* 2002;76:442–446
66. Obermayer-Pietsch BM, Bonelli CM, Walter DE, et al. Genetic predisposition for adult lactose intolerance and relation to diet, bone density, and bone fractures. *J Bone Miner Res.* 2004;19: 42–47
67. During MJ, Xu R, Young D, Kaplitt MG, Sherwin RS, Leone P. Peroral gene therapy of lactose intolerance using an adeno-associated virus vector. *Nat Med.* 1998;4:1131–1135
68. Sanders ME, Klaenhammer TR. The scientific basis of *Lactobacillus acidophilus* NCFM functionality as a probiotic. *J Dairy Sci.* 2001;84:319–331
69. Johnson JD. The regional and ethnic distribution of lactose malabsorption. In: Paige DM, Bayless TM, eds. *Lactose Digestion: Clinical and Nutritional Implications.* Baltimore, MD: Johns Hopkins University Press; 1981:11–22
70. US Department of Agriculture. National nutrient database for standard reference. Available at: www.nal.usda.gov/fnic/foodcomp/search. Accessed August 18, 2005
71. Matthews RH, Pehrsson PR, Farhat-Sabet M. Sugar content of selected foods: individual and total sugars. US Department of Agriculture, Human Nutrition Information Service; 1987. Available at: www.nal.usda.gov/fnic/foodcomp/Data/Other/herr48.pdf. Accessed August 18, 2005
72. National Digestive Diseases Information Clearinghouse. Lactose intolerance. Available at: http://digestive.niddk.nih.gov/ddiseases/pubs/lactoseintolerance. Accessed August 18, 2005